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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael Wayne Graham and Robert Norman Rice

Serial No.: 10/646,070 Examiner: Whiteman, Brian A.

Filed : August 22, 2003 Art Unit: 1635

For : CONTROL OF GENE EXPRESSION

30 Rockefeller Plaza  $20^{\text{TH}}$  Floor New York, New York 10112 April 27, 2010

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(d) AND STATEMENT UNDER 37 C.F.R. § 1.97(e)

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants direct the 'Examiner's attention to the following documents:

- 1. January 23, 2003 Statutory Declaration of Neil Andrew Smith, including Exhibits NAS1-NAS25, submitted In re Opposition to Australian Patent Application No. 743316, and disclosed in connection with the subject application in October 29, 2007 an Information Disclosure Statement (Exhibit 1);
- 2. May 1, 2008 Declaration Under 37 C.F.R. § 1.131 of Peter Michael Waterhouse, Michael Wayne Graham, Ming-Bo Wang and Neil A. Smith, including Exhibits 1 to 5,

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submitted May 1, 2008 in connection with U.S. Serial No. 09/287,632, filed April 7, 1999, and disclosed in connection with the subject application in a May 11, 2009 Information Disclosure Statement (Exhibit 2);

- May 8, 2008 Declaration Under 37 C.F.R. § 1.131 of Peter Michael Waterhouse, Michael Wayne Graham, and Ming-Bo Wang, including Exhibits 1 to 3, submitted July 2, 2008 in connection with U.S. Serial No. 11/364,183, filed March 1, 2006, and disclosed in connection with the subject application in a May 11, 2009 Information Disclosure Statement (Exhibit 3);
- 4. Currently pending claims of U.S. Serial No. 09/287,632, filed April 7, 1999, particularly claims 63, 64, and 103. Claims 63, 64, and 103 were disclosed in connection with the subject application in their current form in a May 11, 2009 Information Disclosure Statement (Exhibit 4); and
- 5. Currently pending claims of U.S. Serial No. 11/364,183, filed March 1, 2006, particularly claim 39. The prior version of claim 39 was disclosed in connection with the subject application in a May 11, 2009 Information Disclosure Statement (Exhibit 5).

Item 1 was considered by the Examiner in the subject application as indicated by the initialed Form PTO-1449 (Substitute) returned to Applicants with a January 24, 2008 Office Action. Items 2-5 were considered by the Examiner in the subject application as

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indicated by the initialed Form PTO-1449 (Substitute) returned to Applicants with a June 6, 2009 Officé Action.

Items 1-5 are being listed on Form PTO-1449 (Substitute) attached hereto as **Exhibit A**. Copies of items 1-5 are attached hereto as **Exhibits 1-5**, respectively.

In addition, Applicants also direct the Examiner to other declarations by the named inventors made of record in the subject application.

The January 23, 2003 Declaration in paragraph 29 refers to notebook pages submitted as Exhibit NAS24 thereto recording attempts to construct a chimeric DNA encoding a double stranded RNA in the form of a hairpin loop. One chimeric DNA construct described in the notebook pages, if it had been successfully made, would have comprised two copies of a 0.75 kb fragment of the cDNA copy of the Potato Virus Y RNA genome (PVY) in inverted orientation under control of a single 35S promoter and further comprising a non-complementary sequence of about 50 nucleotides between the PVY fragments. The experiments recorded notebook pages submitted as Exhibit NAS24 to the January 23, 2003 Declaration were performed at CSIRO Plant Industry laboratories in Canberra, Australia, i.e. not in this country, by persons not listed as inventors on the subject application prior to the earliest effective filing date of the subject application.

The May 1, 2008 Declaration in paragraphs 4-17 describes with reference to notebook pages submitted as Exhibit 1 thereto the construction of a chimeric DNA comprising two copies of a 0.75 kb

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fragment of the cDNA copy of the Potato Virus Y RNA genome (PVY) in inverted orientation under control of a single CaMV 35S promoter and further comprising intron 2 of the *Pdk* gene from *Flaveria trinervia* in the transcribed region of the chimeric DNA. The intron was approximately 0.77kb in length. The experiments recorded in the notebook pages submitted as Exhibit 1 to the May 1, 2008 Declaration were performed at CSIRO Plant Industry laboratories in Canberra, Australia, i.e. not in this country, by persons not listed as inventors on the subject application prior to the earliest effective filing date of the subject application.

The May 1, 2008 Declaration in paragraphs 18-26 and describes with reference to notebook pages submitted as Exhibits 2 and 4-5 thereto the construction of another construct. construction of the same is also described construct in paragraphs 4-23 of the May 8, 2008 Declaration with reference to Exhibits 1-3 to the May 8, 2008 Declaration. The construct described in both the May 1, 2008 Declaration and in the May 8, 2008 Declaration is a chimeric DNA construct encoding an RNA comprising sense and antisense nucleotide sequences targeted to a β-glucuronidase gene (GUS) in which the sense and antisense nucleotide sequences were designed to basepair over about 558 The construct further comprised a spacer sequence of approximately 1 kb. The experiments recorded in the notebook submitted as Exhibits 2 and 5-6 to the Declaration, and also submitted as Exhibits 1-3 of the May 8, 2008 Declaration (a) were performed at CSIRO Plant Industry laboratories in Canberra, Australia, i.e. not in this country, by persons not listed as inventors on the subject application prior

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to the earliest effective filing date of the subject application, and (b) are the same experiments referred to on at least pages 36 and 38-39 of U.S. Serial Nos. 09/287,632, 11/364,183, and 11/841,737.

In the subject application, the current claims were allowed after being amended July 15, 2009.

The current Assignee of record of the subject application, CSIRO, requested the undersigned attorneys to review whether the correct inventors are listed as to the allowed claims in the subject application prior to paying the issue fee. During my review, I did not identify any information which I found to necessitate a change of inventorship of the subject application. review of inventorship of the allowed claims of the subject application, I first understood within the past three months that the correct inventors of the invention recited by the allowed claims of the subject application are different from the named inventors of the inventions recited by claims of U.S. Serial Nos. 09/287,632, 11/364,183, and 11/841,737, and are different from individuals who conducted the experiments recorded laboratory notebook pages referenced in the January 23, 2003, May 1, 2008 and May 8, 2008 Declarations. Such information may be considered material by an Examiner to the patentability of the allowed claims.

<sup>1</sup> The current Assignee of record had argued that the Australian application which derives from the same PCT International Application as the subject application incorrectly listed inventors of the invention claimed therein under Australian law. See, e.g. Statement of Grounds and Particulars of Opposition, submitted in In re Opposition to Australian Patent Application No. 743316, which was disclosed in the October 29, 2007 Information Disclosure Statement filed in connection with the subject application.

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In accordance with 37 C.F.R. \$1.97(e), my understanding that the correct inventors of the invention recited by the allowed claims of the subject application are different from the named inventors of the inventions recited by claims of U.S. Serial Nos. 09/287,632, 11/364,183, and 11/841,737, and are different from the individuals who conducted the experiments recorded in the laboratory notebook pages referenced in the previously considered January 23, 2003, May 1, 2008 and May 8, 2008 Declarations, was not known to me and, to my knowledge after making reasonable inquiry, to any individual designated in 37 C.F.R. \$1.56(c) more than three months prior to the filing of this Supplemental Information Disclosure Statement.

According to 37 C.F.R. § 1.97(d), a Supplemental Information Disclosure Statement filed after the period specified in 37 C.F.R. § 1.97(c) shall be considered if accompanied by the fee set forth in 37 C.F.R. § 1.17(p) and a statement under 37 C.F.R. § 1.97(e). The required fee set forth in 37 C.F.R. § 1.17(p) is one hundred eighty dollars (\$180.00) and a check for this amount is enclosed. A statement under 37 C.F.R. § 1.97(e) appears above. Accordingly, this Supplemental Information Statement shall be considered.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, other than the enclosed fee of \$180.00, is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

our J. Heuslick

hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop Amendment Commissioner for Patents P.O. Box 1450

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## **EXHIBIT A**